

**REMARKS**

Claims 1-46 will be pending upon entry of this amendment. The support for amendments and new claims in this response and can be found in the specification at, among other places, page 2, line 25 to page 3, line 2; page 4, lines 10-12 and lines 15-16; page 4, line 22 to page 6, line 14; page 12, line 21 to page 19, line 8; page 19, line 9 to page 22, line 26; page 21, lines 1 to 11; page 10, line 16 to page 11, line 2; page 11, line 19; page 16, lines 6-9 and page 23, lines 27-29. Applicants submit that no new matter has been introduced by this amendment.

**Rejection under 35 U.S.C. §112, second paragraph**

Claims 1-21 were rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Claims 1 and 17 were amended to more particularly claim what Applicants consider to be their invention. In particular, the Examiner rejected claims 1 and 17 as missing the identity of the compound to be used in the claimed methods. Applicants have amended the claims to more distinctly identify the compound to be used to practice the method of invention. As amended, the compound used to practice the method of invention is specified to be a compound which comprises a partially demethoxylated polygalacturonic acid interrupted with rhamnose residues. The amended claims recite a class of compound with particularity. The support for the amendment can be found in the specification and the original claims, among other places, page 2, line 25 to page 3, line 2; page 4, lines 10-12 and lines 15-16; page 4, line 22 to page 6, line 14.

The specification describes the chemical properties and the general structure of this type of compound with particularity. Applicants respectfully bring the Examiner's attention to MPEP 2173, which states the primary purpose of the definiteness requirement is to ensure that the scope of the claims is clear so that the public is informed of the boundaries of what constitutes infringement of the patent. The fact that many compounds, which are not all specifically described in the specification, are within the scope of the claims does not make the claims indefinite; the test is whether a skilled artisan can discern whether a particular compound falls within the scope of the claim. "If those skilled in the art can tell whether any particular [compound] is or is not within the scope of a claim, the claim fulfills its purpose as a definition." *In re Miller*, 441 F.2d 689 (CCPA 1971) Applicants submit that the amended claims

unambiguously describe a class of chemical structures and allow a skilled artisan reading them to readily determine whether any given compound is a compound encompassed by the claims.

The Examiner also rejected claims 6-11 and 21, stating the terms “modified,” “pH modified” and “thermally modified” are indefinite. Applicants submit that these terms, used in context as “modified pectin,” “pH modified pectin” and “thermally modified pectin,” are definite and clearly defined in the specification. See page 5 line 22 – page 6 line 14. Accordingly, Applicants submit that one of skill in the art would readily have understood the meaning of these terms as they are used in the present specification and claims.

Claims 4 and 19 were rejected for alleged indefiniteness of the terms “substantially” and “interrupted.” Additionally, claims 5 and 20 were rejected for alleged lack of clear definition of the term “side chains.”

Applicants respectfully disagree. Claim needs to define the patentable subject matter with a reasonable degree of particularity and distinctness. MPEP 2173.02, emphasis in original. It is well established that the term “substantially” does not render a claim indefinite. *In re Nehrenberg*, 280 F.2d 161 (CCPA 1960); *In re Mattison*, 509 F.2d 563 (CCPA 1975); *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819 (Fed. Cir. 1988). Please see also MPEP 2173.05(b) Subsection D. Modified pectin is prepared by partial hydrolysis of naturally occurring pectin, which is heterogeneous in degree of methoxylation and molecular structure. The pH and/or thermal treatment breaks the oxygen-carbon bonds that link the saccharides together and cleaves the methoxy group on the saccharides. Although the methyl ester bond is more labile than the saccharide bonds, a reproducible amount of methyl esters remain after hydrolysis when the treatment is carried out under a condition that will not completely hydrolyze the backbone saccharide bonds for retaining certain average molecular weight of the resulting modified pectin. Put differently, it is practically impossible to have “modified pectin” with complete demethoxylation: an attempt to do so results in oligo- or mono-saccharide mixture. In addition, because of the originally heterogeneous population of molecules, it is also not possible to precisely numerically express the degree of demethoxylation. Applicants submit that one of ordinary skill in the art would understand the meaning of “substantially demethoxylated.” As for the terms “interrupted” and “side chains,” Applicants submit that these terms were well

known and accepted in the art at the time of filing the instant application as describing unambiguous structures. The Merck Index, which was cited in the office action, describes pectin as “the partial methyl ester of  $\alpha$ -(1 $\rightarrow$  4) linked D-polygalacturonate sequences *interrupted with* (1 $\rightarrow$  2)-L-rhamnose residues. Neutral sugars: D-galactose, L-arabinose, D-xylose and L-fucose form *side chains* on the pectin molecule.” (Emphasis added) There is no further description or definition of these terms in this very basic and widely used reference, indicating that these terms were readily understood by those skilled in the art.

Further, the plain and literal meaning of “interrupted” clearly indicates that the backbone of a compound to be used in the method of invention is not uniformly made of galacturonic acid, but instead contains some rhamnose moieties. Whether a compound is a substantially demethoxylated polygalacturonic acid “interrupted with rhamnose residues” or not is capable of being unambiguously determined by ordinary analytical procedures. The interruption by rhamnose, which is a physical characteristic and not a probabilistic characteristic, is either present or not.

Similarly, the term “side chains” is clear and unambiguous, and has long been used in the chemical field, both for carbohydrates and many other types of molecules. If a carbohydrate has a branching, pendent sugar moiety, it has a side chain. There is no difficulty in discerning the metes and bounds of the claim. One skilled in the art who looks at a compound can readily determine whether the compound has side chains, and whether the side chains end with galactose or arabinose. Applicants’ claims recite a genus of compounds comprising certain galacturonic acid polymers with side chains of various lengths terminating in galactose or arabinose. This characterization is consistent with and entirely appropriate for modified derivatives of naturally occurring molecules such as pectin from various sources, which has been shown to consist of a heterogeneous molecular population which consists of molecules with branches of varying length and degree of branching. See, for example, Round *et al.*, *Carbohydrate Res.* 331: 337-342 (2001) (Exhibit A). Such a heterogeneous population, which is not always easily fractionated by size or by characteristics such as the length of the branch, can nevertheless be treated as a group that shares certain structural characterization and gives reproducibly consistent physiological results. The group can be fairly described as having certain terminal sugar units, which are well-defined, and which give rise to the physiological

effects. Applicants submit that a description of a population of molecules that is not limited to a particular branch length or composition describes a group of molecules sharing distinct characteristics with a reasonable degree of particularity and distinctness. See MPEP 2173.02. Accordingly, to satisfy the requirement of 35 U.S.C. § 112 second paragraph, it is not necessary to specify the length of the side chains. Additionally, breadth of a claim does not make it indefinite. *In re Miller*, 441 F.2d 689, 169 (CCPA 1971). See also MPEP 2173.04. The amended claims recite a compound with distinct structural elements recognizable by one skilled in the art, and clearly indicate the metes and bounds of the claims so that one skilled in the art can readily assess infringement. See *Morton Int'l Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993). As cited above, primary purpose of the definiteness requirement is to ensure that the scope of the claims is clear so that the public is informed of the boundaries of what constitutes infringement of the patent. Therefore, these claims satisfy the definiteness requirement of 35 U.S.C. § 112, second paragraph. The terms “interrupted” and “side chains” meet that requirement. Applicants respectfully request that this ground of rejection be withdrawn.

Double Patenting Rejection

Claims 1-10, 12-15, and 17-21 were provisionally rejected as claiming the same invention as the claims of U.S. Application No. 10/299,478. Claims 1 and 17 are presently amended to more particularly claim what Applicants consider to be their invention, and to be distinct from the invention claimed in the cited application.

Obviousness-type Double Patenting Rejection

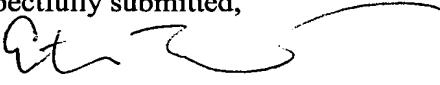
Claims 11 and 16 were provisionally rejected as not patentably distinct from claims 12-15 and 31 of U.S. Application No. 10/299,478. When patentable subject matter is identified, Applicants will consider whether to file a terminal disclaimer to overcome this ground of rejection.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. GLYO-P02-007 from which the undersigned is authorized to draw.

Dated: May 9, 2005

Respectfully submitted,

By   
\_\_\_\_\_  
Erika Takeuchi

Registration No.: 55,661  
Fish & Neave IP Group  
ROPES & GRAY LLP  
1251 Avenue of the Americas  
New York, NY 10020-1104  
(212) 596-9479  
(212) 596-9090 (Fax)  
Attorneys/Agents For Applicant